**REMARKS**

All claims pending and not withdrawn, Claims 93,94 and 132 – 134 stand rejected on a single ground, for lack of enablement. These claims, each directed, in varying scope, to a method for inhibiting HIV particle generation by contacting a cell potentially infected with HIV with a peptide that inhibits binding between TSG101 and the HIV Gag polypeptide are rejected because the Examiner maintains that because there is only a single example, and "there is no other *in vitro* or *in vivo* working example that shows the effectiveness of any other PTAP-containing peptides" one of skill in the art would not be able to practice the invention over its entire scope. Office Action, page 4. The examiner further rests her basis for rejection on the lack of showing that any particle meeting the described function can be prepared. Office Action, page 8 -9. Respectfully, the Examiner is wrong as a matter of law. The Patent Office has already made the determination that the specification of the above-captioned application is enabling, to one of ordinary skill in the art, to identify and use a peptide that is effective in reducing HIV particle formation wherein the peptide comprises the PTAP motif of an HIV Gag protein, including but not limited to the peptide of SEQ ID NO: 4. More is not required for enablement of the pending claims.

**REQUEST FOR CLAIM CONSTRUCTION**

Before turning to the specifics of a rejection for enablement, and the presumption of enablement applicable herein, Applicants respectfully request that if prosecution is to be continued, the Examiner's construction of the pending claims, in accordance with prevailing law, be advanced as a discrete understanding. Respectfully, the Examiner has defined the **current pending and not withdrawn claims** broadly, and then when confronted by persuasive evidence

of enablement, construed the claims narrowly to exclude that evidence. While, as is discussed below, the evidence remains compelling, the law looks to the file history to interpret patent claims. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323, 75 USPQ2d 1321 (Fed. Cir. 2005) (en banc) [6] *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1371-72, 68 USPQ2d 1161 (Fed. Cir. 2003), *Augustine Med., Inc. v. Gaymar Indus., Inc.*, 181 F.3d 1291, 1300, 50 USPQ2d 1900 (Fed. Cir. 1999). The current history is confused.

As noted in Applicants' prior submission, the Examiner has previously characterized the claims as embracing, *inter alia*, the use of antibodies that bind to TSG101 on the surface of HIV infected cells. Applicants submitted evidence of the effectiveness of this method as preventing infection and the formation of HIV particles. The Examiner now responds that "This sentence is lifted out of context in Examiner's office action mailed on 8 August 2007…Since applicant amended the claims and added the limitation "wherein said compound is a peptide comprising a PTAP motif" the aforementioned sentence is no longer the Examiner's position." Office Action, page 9. Respectfully, this confuses the matter.

Applicants introduced the limitation that the compound in question is a PTAP peptide in their amendment of May 29, 2007. The examined claims have not been altered in that respect since. In the Action of August 8, 2007, rejecting those claims, the Examiner "maintained and extended" this rejection expressly stating, again, that the breadth of the claims embraces the use of antibodies. Office Action of August 8, 2007, page 3. Since that time, the Examiner has not otherwise construed or characterized the claims.

Applicants' concern arises because the outstanding Action acknowledges that Applicants' disclosure as originally filed DOES enable:

"a method for identifying all PTAP-containing peptides that are effective at inhibiting the binding between Tsg101 and the HIV Gag protein and thereby blocking the HIV particle generation in the virus lift cycle."

Respectfully, that is all Applicants claim – using such a particle to inhibit particle formation (Applicants do not specify the virus lift cycle in part because it is unclear if HIV exhibits such a cycle, per se). It is unclear, if Applicants' enabling disclosure is commensurate in scope with the claims, where the rejection arises from. Accordingly, claim construction is requested.

**RESPONSE TO REJECTION**

The Examiner maintains the rejection NOT because one of skill in the art is not enabled to identify suitable peptides – the Examiner concedes it does. The Examiner maintains the rejection not because the disclosure does not have an example of the effectiveness of these peptides – the Examiner concedes that it does. Office Action, pages 8 – 9. The Examiner does NOT maintain the rejection because the disclosure lacks a teaching of how to administer such a peptide to a cell – indeed, it has abundant disclosure, and the Examiner does not find fault with any of it. See, for example, pages 17 – 18 for *in vivo* administration, and pages 19 – 30 for *in vitro* and generic administration. Applicants even disclose an example demonstrating the effectiveness of the invention – see pages 33 – 39.

The Examiner maintains the rejection for different reasons entirely. The Examiner maintains the rejection because the prior art shows that the therapeutic treatment of HIV in humans is unpredictable. It is. This is **NOT** what Applicants claim. There is no recitation in Applicants' examined claims about treating HIV, about a therapeutic level of effectiveness, about human conditions, or any of the other concerns expressed by the Examiner. This is not a

feature of Applicants' claims. The Examiner offers absolutely no argument or discussion of why the administration to a cell, *in vivo*, of the disclosed peptides, should work in different fashion than shown. The factors the Examiner expresses concern over – molecular determinants, clinical efficacy predictions, lack of acceptable pharmacological profiles, failure of related structural analogs (page 5 of the Outstanding Office Action)- are respectfully submitted to be beside the point. Applicants claim only that which they have demonstrated – that administration of the claimed peptides to the cell-inhibition of HIV particle formation.

At page 6 of the Office Action, the Examiner discusses prior art efforts in connection with protease inhibitors. Respectfully, again, the Examiner is not addressing the presented claims. First, Applicants note there are some 12 or 13 accepted protease inhibitors for AIDS. AIDS is not HIV infection – the two are not the same. Moreover, the problems identified – drug resistant mutations, non-adherence, poor pharmacokinetics – have no relevance here. Applicants are not addressing a cure for AIDS, and not claiming the same. Moreover, they are not targeting HIV – as set forth in the specification as originally filed, by interfering with binding between the virus and a surface molecule, a method of inhibiting particle formation (the binding is required for particle formation) without putting selection pressure on the virus is provided.

Respectfully, unless and until the Examiner can forward, not issues encountered in prior art HIV cures, but a reason one of skill in the art would not expect the particles enabled herein to do exactly what they are shown to do, in some *in vivo* setting, there is no basis to reject the claims. An applicant can be held to enable ONLY that which he claims, not want someone hopes what his claims may come to offer others.

**The Claims Are Enabled as a Matter of Law**

U.S. Patents are presumed enabling as to the inventions set forth therein. *Amgen. Inc v. Hoechst Marion Roussel, Inc.*, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003), Sanofi v. Synthelabo, 89 USPQ2d 1370, 1376 (Fed. Cir. 2008). This application is identical in content to the application supporting U.S. Patent 7,494,767, issued February 24, 2009. The claims of that application, and the invention disclosed therein, call for identifying peptides with a PTAP motif that inhibit binding between TSG101 and HIV Gag, and thereby inhibit particle formation. The disclosure describes the inhibition of particle formation *in vivo* and *in vitro*. This is all that Applicants claim. The Patent Office cannot now retreat from the position that the disclosure of the above-captioned application, identical in all respects with the disclosure of the '747 patent, does not enable the method of making and using the peptides identified by the claims of that application – this is the standard of law, what is meant by enablement. The sole use described is the inhibition of particle formation – *in vivo* and *in vitro*. While the presumption can be overcome, no evidence has been advanced to overcome it, and Applicants respectfully submit that the PTO is in a poor position to do so, having issued the '747 patent only one day ago.

**The Antibody Data Is Relevant**

Applicants submitted data demonstrating that blocking binding between TSG101 and HIV, as well as other viruses, can inhibit particle formation and infection. The Examiner disregards this evidence on the ground that "the antibodies do not meet the present claim limitations of a peptide comprising a PTAP motif." Action, page 9. Respectfully, no matter how the Examiner construes the claims, the evidence is relevant. At pages 7 – 8 of the Office Action of November 25, 2008, the Examiner argues that Applicants have provided insufficient evidence

to demonstrate that interfering in the binding between Tsg101 and HIV actually results in reduced particle formation. While Applicants disagree, and the issuance of the '747 patent would seem to indicate otherwise, in fact, that is EXACTLY what the antibodies in question do. They prevent binding between HIV and the TSG101 protein (like the peptides of the claimed invention, they combine with the TSG101 hijacked to the cell surface by the virus) and thereby inhibit particle formation, and infection. Thus, whether viewed *in vivo* or *in vitro*, if you concede that the peptides of the invention inhibit particle formation, there is abundant evidence of record that clearly demonstrates that notwithstanding prior art issues, even IF demonstration of anti-AIDS efficacy was required, the peptides claimed will exhibit that efficacy.

For all of the above reasons, the rejection of pending Claims 93, 94 and 132 – 134 is traversed, and respectfully, its withdrawal is requested. Applicants continue to be of the position that the outstanding restriction position of the Office is without foundation. Searching all the claims, given the file history of this application and the parent '747 patent would not impose an undue burden. Notwithstanding, should the examiner find the examined claims allowable, she is hereby authorized to cancel all non-considered pending claims.

**CONCLUSION**

In view of the foregoing evidence and remarks, Applicants respectfully request withdrawal of the single outstanding rejection, reconsideration of this Application and the prompt allowance of at least Claims 93, 94 and 132-134.

Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the undersigned to expedite prosecution of the application.

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 10-0233.

Date: February 25, 2009

Respectfully submitted,

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